EXHIBIT 10

EXPERT DECLARATION OF DR. MICHAELA ALMGREN

I. Background and Qualifications

1. My name is Michaela Almgren, Pharm.D., M.S. I am over the age of eighteen and competent to testify to the truth of the matters contained herein. The factual statements I make here are true and correct to the best of my knowledge.

2. I am a Clinical Associate Professor in the Department of Clinical Pharmacy and Outcomes Sciences at the University of South Carolina College of Pharmacy. I teach principles of sterile compounding per United States Pharmacopeia ("USP")[1] Chapters 797 and 800, aseptic technique and pharmacy regulations applicable in sterile compounding environment[2] under 503a guidance and section 503b of the Drug Quality and Security Act of 2013, as well as pharmacokinetics, pharmacotherapy, pharmacy law, and biopharmaceutics courses. I specialize in sterile compounding, medication safety and pharmacy laws and regulations that relate to pharmacy compounding practices. I also provide continuing education courses for pharmacists on those topics. I received my Doctor of Pharmacy degree from the University of South Carolina College of Pharmacy in 2010. Additionally, I have a master's degree in Pharmaceutical Chemistry from the University of Florida.

3. In conjunction with my academic appointment, I currently maintain a practice site at a 503b[3] outsourcing pharmacy where I perform duties of an outsourcing pharmacist, clinical advisor and pharmacy student preceptor. Previously, I worked in pharmacy operations

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[1] USP sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements in the United States. The USP publishes the United States Pharmacopeia-National Formulary (USP-NF), which contains a compendium of quality standards and specifications for a wide range of pharmaceuticals and related products. USP Chapters 797 and 800 are part of the USP-NF compendium.

[2] Aseptic technique in drug compounding refers to specific practices to avoid physical and microbial contamination when preparing sterile medications that are to be used for parenteral applications, such as IV infusion, injection, etc.

[3] 503b Outsourcing Pharmacy is a compounding pharmacy that produces large batches of sterile products and distributes them directly to health systems pharmacies to address drug shortages, as specified in Section 503B of the FD&C Act.

at a large local teaching hospital as a pharmacist. I have over fifteen years of experience in sterile compounding and aseptic technique. Prior to joining the faculty at the University of South Carolina I worked for several years in pharmaceutical manufacturing where I was involved in drug formulation, quality assurance, quality control and analytical method development and validation. My professional qualifications are Doctor of Pharmacy and Master of Science in Pharmacy with focus on Pharmaceutical Chemistry. A copy of my CV is attached as Exhibit A.

4. I have been asked by the Federal Defender Services of Idaho ("FDSI"), who represent death-sentenced prisoner Gerald Ross Pizzuto, Jr. to submit an expert medical and scientific opinion based on the information and documentation provided to me about the issues surrounding pharmaceutical quality of manufactured drug products and factors that may impact drug quality of marketed medications obtained from non-traditional supply channels.

5. Historically, the American and European companies that have manufactured pentobarbital have refused to sell the drug for execution purposes, adamantly opposing the use of their products in capital punishment. These manufacturers have generally been quite rigorous about enforcing the execution-related restrictions in their contracts. Some of these companies have taken the drastic step of ceasing the production of their drugs to prevent any possibility of their products being utilized in executions.[4] Additionally, certain manufacturers, such as Fresenius Kabi, have initiated legal actions to prevent the use of their drugs in execution procedures.[5]

6. When drugs are obtained in violation of the kind of distribution restrictions described above, it increases the risk that the chemicals will be unreliable. Such violations often

[4] https://dpic-cdn.org/production/legacy/HospiraJan2011.pdf

[5] https://www.theguardian.com/us-news/2018/aug/08/german-drug-maker-sues-to-halt-planned-execution-in-nebraska

make chains of custody longer, so that the recipient is better able to conceal the original source. If a chain of custody becomes longer, there is more opportunity for drugs to be mishandled, improperly stored, transported under inappropriate conditions, and so forth. Those dangers are further enhanced by the fact that, when drugs begin moving outside of the usual lawful channels, there is a greater chance that they will be controlled by individuals who are unconstrained by the applicable regulatory framework, not following the proper procedures, and who do not have the necessary facilities or qualifications to handle medications correctly.

7. Foreign manufacturing sources may sometimes be considered for obtaining lethal injection medications. Regrettably, companies in certain regions of the world, like India and China, are more prone to encountering quality issues. Reports suggest that data falsification and manipulation are common practices in pharmaceutical manufacturing plants located in India and China.[6] The U.S. Food and Drug Administration's (FDA's) Foreign Inspection Program is falling short in uncovering a substantial amount of fraud in overseas plants due to its approach to inspections. While FDA investigators in the United States conduct unannounced inspections, overseas inspections are pre-announced, providing plants with the opportunity to rectify any evidence of unsanitary conditions, data manipulation, and other significant quality issues. This increases the strong likelihood that medications and Active Pharmaceutical Ingredients (APIs)[7] manufactured overseas may exhibit significant quality problems due to insufficient oversight by U.S. regulatory agencies.

8. Recently, medications produced abroad have been found to be contaminated and failing to meet the quality standards set by the FDA and USP. Following a nearly two-year decrease in overseas inspections due to the pandemic, inspectors from the FDA discovered

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[6] https://www.statnews.com/2019/10/29/data-falsification-still-problematic-china-india-generic-drug-plants/

[7] API stands for Active Pharmaceutical Ingredient. It refers to the biologically active component of a pharmaceutical drug. The API is the substance responsible for the therapeutic effects of the medication.

widespread quality violations upon their return to the facilities operated by some of the major pharmaceutical companies outside of the United States. Numerous significant issues related to the quality of drugs led to the recall of several pharmaceutical products.[8]

9. However, even medications manufactured in the U.S. can sometimes raise quality concerns. Until recently, Akorn Pharmaceuticals was one of several companies that manufactured pentobarbital for injection in the United States. In February 2023, Akorn announced that it was declaring bankruptcy, closing all of its U.S. sites, and laying off all of its employees. When it was still functioning, Akorn opposed the use of its products in executions. It is possible that the bankruptcy of Akorn complicated the company's ability to enforce—or its interest in enforcing—the execution-related restrictions in its contracts.

10. I would have serious concerns about the quality of any pentobarbital made by Akorn and intended for use in an execution. Prior to its bankruptcy, Akorn Pharmaceuticals had received numerous FDA Forms 483[9] and Warning Letters, indicating significant concerns about the quality of their drugs. The company was known to submit fraudulent test results to the FDA, as well as manipulated testing data, often "testing into compliance"—the practice where the drug is tested repeatedly until a passing result is achieved, and even reporting fabricated data, where the results of testing were reported despite the fact that the laboratory did not own the equipment necessary to perform the testing. Some other extremely troubling examples of Akorn's unacceptable quality control and assurance practices included their insufficient data integrity controls lacking audit trail leading to inability to prevent unauthorized changes to electronic quality control information. This led to the possibility that all of their data could be questionable and subject to potential manipulation. The pervasive lack

[8] https://www.livemint.com/companies/news/sun-pharma-lupin-recall-drugs-in-us-over-manufacturing-issues-usfda-11702795716102.html.

[9] The FDA Form 483 notifies the company's management of objectionable conditions and serious quality violations at the time of the FDA inspection.

of a quality-oriented culture persisted in Akorn for an extended period over many years, making it unsurprising that the company faced bankruptcy. The extensive nature of their quality issues went beyond the scope of manageable resolution. The reports from FDA from the last on-site audit[10] (December 21st, 2022) before the company closed signalled serious problems—buildings where the sterile medications were manufactured were not maintained in sanitary conditions, representative samples of each shipment were not taken, process controls were not being followed and "the equipment was not maintained causing malfunction resulting in alterations in the safety, identity, quality or purity of the drugs produced." The list of quality problems discovered during that FDA audit was extremely concerning. However, no corrective actions were taken as the company filed for Chapter 7 bankruptcy in February 2023. Given this information, it would be unsurprising if the medications manufactured by Akorn fail to meet the established quality standards.

11. As mentioned above, the fact that a drug is classified as "manufactured" does not ensure that it has been made correctly or is effective. The safety, efficacy, and quality of drugs rely on the manufacturer's strict compliance with regulatory standards and manufacturing practices set by the FDA, as well as proper storage and handling.

12. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 17th day of October 2024.

Michaela M. Almgren

Dr. Michaela M. Almgren

[10] https://datadashboard.fda.gov/ora/cd/inspections.htm